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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,025	01/16/2004	Jean Hildesheim	1662/636021	6234

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WASHINGTON, DC 20005

EXAMINER

SAEED, KAMAL A

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,025

Applicant(s)

HILDESHEIM ET AL.

Examiner

Kamal A Saeed

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-83 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 22-83 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 22 and 23, are drawn to crystalline carvedilol , classified in class 548, and several subclasses.
 - II. Claims 24, 28, and 29, are drawn to crystalline carvedilol (methyl-ethyl-ketone) solvate and a composition thereof, classified in class 548, and several subclasses.
 - III. Claims 25, 26 and 27, are drawn to crystalline carvedilol Form III, classified in class 548, and several subclasses.
 - IV. Claims 30 and 31, are drawn a method of use of crystalline carvedilol Form III, classified in classes 548, and several subclasses.
 - V. Claims 32-34, are drawn to crystalline carvedilol (methyl-ethyl-ketone) solvate Form V, classified in class 548, and several subclasses.
 - VI. Claims 39-42 and 83, are drawn to crystalline carvedilol HCl hydrate, classified in class 548, and several subclasses.
 - VII. Claims 43-53, are drawn to a process of preparing crystalline carvedilol Form I, classified in class 548, and several subclasses.
 - VIII. Claims 54-67, are drawn to a process of preparing crystalline carvedilol Form II, classified in class 548, and several subclasses.
 - IX. Claims 68-73, are drawn to a process of preparing crystalline carvedilol Form IV, classified in class 548, and several subclasses.

Art Unit: 1626

- X. Claims 74-77, are drawn to a process of preparing crystalline carvedilol Form V, classified in class 548, and several subclasses.
- XI. Claims 79-82, are drawn to a second process of preparing crystalline carvedilol Form V, classified in class 548, and several subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I, II, III, V and VI and Groups VIII-XII are related as process of making and product made. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make another materially different product or (2) that the product as claimed can be made by another materially different process (MPEP 806.05(f)). In the instant case, the product as claimed can be made by another materially different process as is clearly evident from examples 15 and 16 (page 26 of the specification). Therefore a separate search considerations are involved, which would impose a burden if unrestricted.

Inventions of Group I, II, III, V and VI are directed to different forms of carvedilol. These inventions are distinct, each from the other, because they have different physical properties as shown by the results of their X-ray diffraction pattern and differential scanning calorimetry thermal profile and a prior art reference anticipating but one of the groups would not render obvious the other groups under 35 U.S.C. 103.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Additionally, besides performing a class/subclass search, the examiner performs a commercial data base search and an automated patent system

Art Unit: 1626

(text) search. Moreover, to not restrict would impose a burden in the examination of this application.

In accordance with M.P.E.P. 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process or method of use claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until such time, a restriction between product, method of use and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised the process or method of use are amended during prosecution to maintain either dependency on the product claims or to otherwise include limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

A telephone call was made to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed whose telephone number is (703) 308 4592. The examiner can normally be reached on M-F 8:00 AM- 5:00 PM.

The examiner can normally be reached on Monday-Friday from 8:00 AM – 5:00 PM.

Art Unit: 1626

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308 4537. The unofficial fax phone for this group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and " Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-2286.

Kamal Saeed

Kamal Saeed, Ph.D.

Primary Patent Examiner, AU 1626